Joint Formulary Committee (JFC): Minutes

Minutes from the meeting held on 15th August 2024

		Present	Apologies
Members			
Prof A Hingorani (Chair)	NCL JFC Chair	✓	
Dr B Subel	NCL JFC Vice Chair	✓	
Ms L Coughlan	NCL ICB, Deputy Chief Clinical Officer & ICS Chief Pharmacist		✓
Ms W Spicer	RFL, Chief Pharmacist		✓
Dr P Jasani	RFL, DTC Chair		✓
Dr K Boleti	RFL, DTC Chair		✓
Dr A Scourfield	UCLH, DTC Chair	✓	
Mr J Harchowal	UCLH, Chief Pharmacist	✓	
Dr R Urquhart	UCLH, Divisional Clinical Director		✓
Dr K Tasopoulos	NMUH, DTC Chair	✓	
Ms S Stern	NMUH, Chief Pharmacist	✓	
Dr M Kelsey	WH, DTC Chair	✓	
Mr S Richardson	WH, Chief Pharmacist	✓	
Dr S Ishaq	WH, Consultant Anaesthetist		✓
Dr A Worth	GOSH, DTC Chair		✓
Ms J Ballinger	GOSH, Chief Pharmacist		✓
Dr M Henley	RNOH, DTC Chair		✓
Mr A Shah	RNOH, Chief Pharmacist		✓
Prof A Tufail	MEH, DTC Chair		✓
Ms N Phul	MEH, Chief Pharmacist		✓
Ms K Delargy	NLMHP, Partnership Deputy Chief Pharmacist	✓	
Ms L Reeves	NLMHP, Chief Pharmacist		✓
Dr L Waters	CNWL, Consultant Physician in HIV	✓	
Ms R Clark	NCL ICB, Assistant Director of Medicines Optimisation		✓
Ms M Kaur-Singh	NCL ICB, Head of Medicines Planning & Operations	✓	
Dr D Roberts	NCL ICB, Clinical Director (Islington)	✓	
Ms EY Cheung	NCL ICB, Head of Quality and Improvement		✓
Ms K Petrou	NCL ICB, Community Pharmacy Clinical Lead	✓	
Dr S Ghosh	Enfield Unity PCN, Clinical Director; Enfield GP Federation, Co-Chair	✓	
Dr D Heaney	UCLH, Consultant Neurologist	✓	
Mr S Jenkinson	RFL, Lead Pharmacist Cancer Services	✓	
Attendees			
Ms S Sanghvi	IPMO Programme Team, JFC Principal Pharmacist	✓	
Ms S Amin	IPMO Programme Team, Lead Pharmacist		✓
Ms S Maru	IPMO Programme Team, JFC Support Pharmacist	✓	
Ms K Leung	IPMO Programme Team, JFC Support Pharmacist	✓	
Ms M Butt	IPMO Programme Team, Director	✓	
Ms I Samuel	RFL, Formulary Pharmacist	✓	
Mr H Shahbakhti	RFL, Formulary Pharmacist	✓	
Mr A Barron	UCLH, Principal Pharmacist	✓	
Mr S O'Callaghan	UCLH, Formulary Pharmacist	✓	
Ms H Thoong	GOSH, Formulary Pharmacist	✓	
Mr D Sergian	MEH, Formulary Pharmacist	✓	

Mr W Li	MEH, Formulary Pharmacist	✓	
Ms J Bloom	MEH, Associate Chief Pharmacist	✓	
Ms A Bathia	RNOH, Formulary Pharmacist	✓	
Ms S Ahmed	WH, Formulary Pharmacist	✓	
Ms N Patel	NMUH, Formulary Pharmacist	✓	
Ms M Thacker	GOSH, Deputy Chief Pharmacist	✓	
Ms H Weaver	NHSE, Specialised Commissioning Pharmacist		✓
Ms R Allen	UCLH, Commissioning Pharmacist	✓	
Dr M Amran	Clinical Pharmacology Registrar	✓	
Ms A Husain	UCLH, Lead women's Health and Neonates Pharmacist	✓	
Dr M Thomas	UCLH, Consultant Haematologist	✓	
Ms J Pang	IPMO Programme Team, Lead Pharmacist	✓	
Mr A Fazal	RFL, Principal Pharmacist	✓	
Ms C Gates	UCLH, Thrombosis and Anticoagulation Pharmacist	✓	
Mr K Cahill	RFL, Deputy Chief Pharmacist	✓	
Ms L Antona	GOSH, Senior Specialist Pharmacist	✓	
Ms K Rajani	GOSH, Rheumatology and Dermatology Specialist Pharmacist	✓	
Ms T Begum	IPMO Programme Team, Community Pharmacy Integration Project Manager (Observer)	✓	
Ms A Abdullahi	RFL, Senior Clinical Commissioning Pharmacist (Observer)	✓	
Ms J Collins	WH, Formulary Pharmacist (Observer)	✓	
Ms M Darjee	NMUH, Gastroenterology Pharmacist (Observer)	✓	

2. Meeting attendees

Prof Hingorani welcomed members, observers, and applicants to the meeting (see above). Ms Cheung (NCL ICB Head of Quality and Improvement), Ms Petrou (NCL ICB, Community Pharmacy Clinical Lead), Dr Ghosh (Enfield GP Federation and Enfield Unity PCN, Clinical Director), Dr Heaney (UCLH, Consultant Neurologist), and Mr Jenkinson (RFL, Lead Pharmacist Cancer Services) were welcomed as new members of the Committee.

3. Members' declaration of interests

The Declarations of Interests register for Committee members was included for information. No further interests relevant to the agenda were raised.

4. Minutes of the last meeting

The decision regarding gastroprotection in patients on high-dose steroids for immune checkpoint inhibitor toxicities was noted to be for famotidine, which is currently the cheapest H2 antagonist and not subject to supply issues. In the event of supply issues or significant changes to drug prices, it was noted that all H2 receptor antagonists are considered to have equivalent efficacy and safety generally, but that the evidence base for this indication is limited and uncertain. Minutes and abbreviated minutes of the July 2024 meeting were ratified.

5. Review of action tracker

Action tracker included for information. Closed actions have been updated on the tracker.

6. JFC Outstanding items and workplan

These items were included for information only. Any questions should be directed to Ms Sanghvi.

6.1 Licensed varenicline availability

Varenicline is recommended for use as a treatment option for smoking cessation in adult smokers under NICE TA123. In 2021, varenicline was withdrawn from the market due to unsafe levels of nitrosamines. In January 2024, unlicensed varenicline (Apotex®) was approved by the JFC for use in secondary care only due to limited supplies and it being unlicensed. In May 2024, the Committee approved the addition of cytisine to the NCL Joint Formulary following a surveillance report that has prompted inclusion of cytisine to the NICE guideline on tobacco. The Committee noted that current evidence suggests cytisine and varenicline have equivalent efficacy and safety but varenicline was currently only available as an unlicensed product at a higher cost compared to cytisine, a licensed product. Since cytisine and varenicline both have the same mechanism of

action, with current evidence suggesting equivalent efficacy and safety, if a patient's quit attempt with their first course of either cytisine or varenicline was not successful, a repeat course with the same drug (or the alternative with the same mechanism of action) should only be considered if an investigation into the rationale for why the relapse occurred and whether a re-trial is appropriate.

Licensed varenicline is expected to be available for procurement from August 2024. Due to preference to use a licensed treatment option ahead of an unlicensed treatment option, unlicensed varenicline is no longer deemed a suitable treatment option in NCL and will be removed from the NCL Joint Formulary once supply is established. Licensed varenicline has been included in the NCL Joint Formulary and it is expected that the choice of cytisine or varenicline will be dependent on availability, cost, and patient preference.

7. Local DTC recommendations/minutes

Date	Drug and Indication	DTC Decision and Details
June 2024	[EAM Scheme] Leniolisib for activated phosphoinositide 3-kinase delta syndrome (APDS)*†	**Reviewed by**: RFL **Drug**: Leniolisib; 70mg twice daily (long-term) **Indication**: Activated phosphoinositide 3-kinase delta syndrome (APDS) **Decision**: Approved **Prescribing status**: Restricted to secondary care only **Funding source**: EAM Scheme **Additional information**: RFL Trust legal team to review the FOC scheme contract from the manufacturer. To be referred to the LEC(s) for funding consideration. **Fact sheet or shared care required**: N/A
June 2024	Ustekinumab for Behcet's like disease related to chronic granulomatous disease*	**Reviewed by**: RFL **Drug**: Ustekinumab; 90mg on weeks 0, 4, 16, then 28 and 40 if response at week 24; following that be re-assessed **Indication**: Behcet's like disease related to chronic granulomatous disease **Decision**: Approved **Prescribing status**: Restricted to secondary care only **Funding source**: Internal Trust funding **Additional information**: To be referred to the LEC(s) for funding consideration. **Fact sheet or shared care required**: N/A
August 2024	SayanaPress® for contraception	**Reviewed by**: JFC **Drug**: SayanaPress® **Indication**: Contraception **Decision**: Approved in line with NCL Prescribing Recommendations for Primary Care **Prescribing status**: Suitable for primary and secondary care initiation **Funding source**: In tariff **Additional information**: N/A **Fact sheet or shared care required**: N/A

*Subject to funding consideration; †The relevant commissioner should be notified in line with NCL Free of Charge scheme guidance. Approval is conditional on the provision of a free of charge scheme agreement and funding statement.

7.2 Botulinum toxin type A: Ratification of previously CCG-commissioned indications in adults

The Committee noted that in 2016, Camden CCG/NEL Commissioning Support Unit (CSU) signed the NHS provider contract which included the provider list of PbRe drugs in the 'CCG commissioned PbRe drugs and devices policy 2016/2017'. In 2022, botulinum toxin type A was no longer considered high cost and therefore removed from the CCG PbRe list. Botulinum toxin type A used in line with the below indications for adults was therefore internally funded by NCL Trusts with an activity tariff uplift to account for the change in commissioning from being a high-cost drug to in tariff. The Committee ratified the previously CCG-commissioned indications for botulinum toxin type A used in adults to the NCL Joint Formulary.

Drug: Botulinum toxin type A

Indications: In line with previously CCG-commissioned indications for use in adults as listed below:

1. In line with NICE for migraine.

2. In line with locally agreed guidelines for:
    a. Spasticity and dystonia including but not limited to human prion disease, stroke, traumatic brain/spine injury and multiple sclerosis
    e. Cranial dystonia
    f. Hypersalivation
    g. Crocodile tears
    h. Ptosis
    i. Hand and jaw cramps
    j. Facial hyperkinetic syndrome

3. In line with locally agreed guidelines for:
    a. Anal fissures
    b. Axillary hyperhidrosis
    c. Severe blepharospasm
    d. Cervical dystonia
    e. Detrusor over activity
    f. Forearm dystonia
    g. Hemifacial spasm
    h. Oesophageal motility disorders
    i. Voice rehabilitation post-op
    j. Sphincter of Odi

4. Voice rehabilitation indications:
    a. Spasmodic / Spastic dysphonia
    b. Tourette's disorder affecting the larynx
    c. Laryngeal granuloma refractory to surgery

Decision: Approved
Prescribing status: Retained in secondary care
Funding source: Internal Trust funding
Fact sheet or shared care required: N/A
Additional information: N/A

8. Matters arising

8.1. Ustekinumab Biosimilar Update

Ustekinumab, currently marketed as Stelara® (Janssen), is used in the treatment of psoriatic arthritis (PsA), Crohn's disease (CD), and ulcerative colitis (UC) in adults and plaque psoriasis in adults and children over 6 years of age. The Committee considered the use of ustekinumab biosimilars for its licensed indications by NCL Trusts. It was noted that biosimilar ustekinumab products are not approved for use in UC; however, this is currently the subject of a legal challenge.

The Committee were informed that a national framework has been agreed for four ustekinumab biosimilars starting September 2024, although only three currently have UK market authorisation. The biosimilars, Pyzchiva®, Uzpruvo®, Wezenla® demonstrated similar efficacy, safety, pharmacokinetic, and immunogenicity profiles to Stelara® as per Feldman et al (2024; n= 503) and Jeong et al (2024; n= 201), Feldman et al (2023; n= 581) and Wynne et al (2023; n= 298), and Chow et al (2023; n= 238) respectively. The Committee further reviewed a product comparison and noted that there were no concerns regarding the biosimilar formulations compared to the originator. Additional biosimilars and variations in presentations are anticipated to become available in the coming months. The Committee were informed that adoption of ustekinumab biosimilars will represent a significant financial saving to the ICB.

The implementation of ustekinumab biosimilars will apply to new and existing patients where biosimilar product licensing allows. Trusts will be responsible for the switch with NCL-wide coordination support offered by the IPMO Programme Team, including drafting an NCL patient leaflet and guidance on product choice to mitigate potential supply issues.

In summary, the Committee approved the use of EMA-approved ustekinumab biosimilars for its licensed indications by NCL Trusts and the NCL biosimilar ustekinumab patient information leaflet for adaptation and use by NCL Trusts.

9. Medicine reviews

9.1. Apixaban for thromboprophylaxis after gynaecological cancer surgery (Applicant: Dr M Thomas, Ms C Gates, Ms A Husain; UCLH)

The Committee considered an application for apixaban (2.5mg twice daily, a direct oral anticoagulant), for off-label extended thromboprophylaxis after gynaecology cancer surgery, as part of a total thromboprophylaxis regimen 28 days, where patients would receive low molecular weight heparin (LMWH) while admitted as an inpatient in hospital, and be discharged on apixaban for the remainder of the course.

Guntupalli et al (2020; n=400) was a multi-centre, 90-day, Phase III, active-comparator controlled, randomized, unblinded non-inferiority trial to compare the efficacy and safety of apixaban and enoxaparin in women undergoing surgery for pelvic malignancy. The co-primary outcome of major bleeding events during the treatment phase and in the 30 days after treatment was not statistically significantly different for apixaban compared to enoxaparin (0.5% vs. 0.5%; OR: 1.04, [95%CI: 0.07 to 16.76]; p>0.99). The co-primary outcome of clinically relevant non-major bleeding events during the treatment phase and in the 30 days after treatment was not statistically significantly different for apixaban compared to enoxaparin (5.4% vs. 9.7%; OR: 1.88, [95%CI: 0.87 to 4.1]; p=0.11). The secondary endpoint, incidence of VTE within 90 days post-surgery, was not statistically significantly different with apixaban compared to enoxaparin (1.0% vs. 1.5%; OR: 1.57, [95%CI: 0.26 to 9.50]; p=0.68). Key limitations of the study were limited patient diversity and lack of applicability to general populations due to being conducted in 2 centres in North America only.

In terms of safety, apixaban is off label for this indication but has a well-known safety profile as per the Summary of Product Characteristics, with bleeding being the most common side effect experienced.

In terms of budget impact, apixaban is expected to save approximately up to £50,000 per annum in NCL, as compared to enoxaparin, with additional potential savings from a reduction in district nurse time required to administer enoxaparin. Apixaban was also noted to offer benefits in relation to patient convenience and reduced healthcare resource utilisation, as an oral preparation with fixed dosing and minimal training requirements and reduced requirement for district nurses and sharps bins for disposal. A lower risk of administration and dosing errors is expected with apixaban versus LMWH.

In camera, the Committee agreed that the evidence shows comparable efficacy and safety. The Committee noted that apixaban is off label for this indication, whereas LMWH would be licensed. However, considering the significant benefits to patient convenience, reduced healthcare utilisation, reduced medication error risk and lower costs overall, it was considered appropriate to recommend off-label apixaban after LMWH in hospital over LMWH alone for extended thromboprophylaxis post-gynaecological cancer surgery.

In summary, the Committee agreed to add apixaban to the NCL Joint Formulary for extended thromboprophylaxis post-gynaecological cancer surgery.

Drug: Apixaban tablets 2.5mg twice daily for a total thromboprophylaxis duration of 28 days; off-label
Indication: Extended thromboprophylaxis after gynaecology cancer surgery
Decision: Approved
Prescribing status: Restricted to secondary care only
Funding source: In tariff
Additional information: N/A

9.2. Botulinum toxin type A for focal relief of muscle spasticity of the limbs, limb dystonia or muscle imbalance in patients > 2 years old (Applicant: Dr D Eastwood; GOSH)

The Committee reviewed a rapid review, *in absentia*, for the off-label use of botulinum toxin type A for focal relief of muscle spasticity of the limbs, limb dystonia or muscle imbalance in patients > 2 years old.

The Committee were informed that botulinum toxin type A has been the standard of care treatment option at RNOH and GOSH for muscle spasticity caused by, but not limited to, cerebral palsy, brachial plexus injury, spinal cord injury and multiple sclerosis. The Committee noted that botulinum toxin type A was previously

commissioned by NHSE for focal spasticity in paediatrics, but botulinum toxin type A was removed from the NHSE High Cost Drug List 22/23.

Evidence of botulinum toxin type A as an established standard of care was provided by its inclusion in standard resources such as NICE Clinical Guidelines (NG145) for spasticity in under 19s, previous NHSE commissioning for this indication, UpToDate and Micromedex. The Committee noted that this was an off-label indication for this cohort as per the MHRA Summary of Product Characteristics (SPC). Evidence was provided that botulinum toxin type A was offered in other NHS services (including GOSH and Evelina) for this indication through the availability of patient information leaflets. The Committee were reassured that there was an appropriate safety profile provided by the MHRA SPC, reporting low-grade common side effects. The Committee noted that GOSH had a local guideline that only included use of botulinum toxin type A for paediatric cerebral palsy spasticity and arm spasticity and would therefore require an update if approved. The annual spend for continuing current practice was not calculated for NCL as patient numbers from GOSH had not been received and the current patient numbers did not account for patients stopping treatment per annum. However, the Committee noted that there was an indication of a slow-growing service at RNOH of approximately 30-40 additional patients per annum.

In camera, the Committee were satisfied that botulinum toxin type A was an established standard of care, with an appropriate safety profile. The Committee queried the estimated patient numbers at GOSH that would transition to adult services and which NCL Trusts the patients would be anticipated to transfer to.

In summary, the Committee approved the use of botulinum toxin type A for focal relief of muscle spasticity of the limbs, limb dystonia or muscle imbalance in patients > 2 years old. This decision was conditional on NCL Trusts confirming patient numbers and considering budget impact locally for internal Trust funding approval.

Post-meeting note: GOSH and RNOH paediatric patients within NCL are expected to be transferred to RNOH adult services only for this indication.

Drug: Botulinum toxin type A
Indication: Focal relief of muscle spasticity of the limbs, limb dystonia or muscle imbalance in patients > 2 years old
Decision: Approved conditional to local financial consideration and approval
Prescribing status: Retained in secondary care
Funding source: Internal Trust funding
Fact sheet or shared care required: N/A
Additional information: NCL Trusts to consider budget impact locally for internal Trust funding approval.

9.3. Ethinylestradiol and etonogestrel ring contraceptive for contraception (Applicant: Dr J Bignall (in absentia); NMUH)

The Committee reviewed the use of ethinylestradiol and etonogestrel vaginal rings (SyreniRing® and NuvaRing®) for contraception. The Committee was informed that the use of ring contraceptives is established practice across primary care in NCL and some sexual health clinics. SyreniRing® and NuvaRing® are equivalent preparations that deliver the same combination of drugs at equivalent doses, but SyreniRing® can be stored at room temperature whereas NuvaRing® must be stored in a refrigerator. There have been reports of supply chain challenges with procuring SyreniRing®, the preferred ring preparation, therefore, this application seeks to add the generic vaginal ring contraceptive to the NCL Formulary to allow for both ring preparations to be supplied where there may be difficulties with procuring one or the other. A rapid review was conducted to assess efficacy and safety of ethinylestradiol and etonogestrel vaginal rings before addition to the NCL formulary to ensure consistency of availability across NCL.

Evidence of ethinylestradiol and etonogestrel vaginal rings as an established contraceptive option was identified in standard resources including the product license, BNF, Micromedex, and Martindale. Ethinylestradiol and etonogestrel vaginal rings were also included in the NICE Clinical Knowledge Summary (CKS) on combined hormonal contraception and in The Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guideline on combined hormonal contraception.

In terms of efficacy, the NICE CKS reports that combined vaginal rings have similar efficacy to combined oral contraceptives and progestogen-only pills. In terms of safety, the product license lists side effects including increased risk of venous thromboembolism and arterial thromboembolism. However, it was noted that the

incidence of adverse events was comparable to other forms of combined hormonal contraceptives. Estimated patient numbers for NCL across primary and secondary care is approximately 700 patients per annum. The anticipated budget impact is expected to be minimal as ethinylestradiol and etonogestrel vaginal rings are already in use in primary care and across some sexual health clinics.

The Committee heard from primary care colleagues that patients' choice of contraceptive is mainly driven by personal preference. The combined hormonal vaginal rings can be self-administered by patients and there are instructional videos online that clinicians can direct patients to. Patients may opt for ethinylestradiol and etonogestrel vaginal rings due to their ease of use and dosing regimen compared to daily oral contraceptives.

In summary, the Committee were supportive of the addition of ethinylestradiol and etonogestrel vaginal rings for contraception to the NCL Joint Formulary.

Drug: Ethinylestradiol and etonogestrel vaginal ring (NuvaRing® and SyreniRing®); as per licensed dose
Indication: Contraception in women of fertile age
Decision: Approved
Prescribing status: Suitable for initiation in primary and secondary care
Funding source: In tariff
Fact sheet or shared care required: No
Additional information: N/A

10. Position Statements and Guidelines

Nil

11. NHSE Updates

Nil

12. Next meeting

Thursday 19th September 2024

13. Any other business

Nil